

REMARKS

This Amendment and Reply is in response to the non-final Office action mailed April 28, 2008. A Petition for an Extension of Time of Two Months and the requisite fee accompany this filing, extending the time for response to **September 28, 2008**. Favorable reconsideration of applicants' pending claims is respectfully requested in view of the above amendments and following remarks. Following the amendments, claims 1-17, 19-21 and 26-28 are pending in the application, with claims 1, 5, 11, and 26 being in independent format.

The specification has been amended, at the **CROSS-REFERENCE TO RELATED APPLICATIONS**, to delete reference to U.S. Application No. 09/826,487, filed April 4, 2001, U.S. Patent Application No. 09/724,914, filed November 28, 2000, and U.S. Provisional Patent Application Nos. 60/194,805, 60/194,952 and 60/194,998 filed April 5, 2000. An amended Application Data Sheet (ADS) is submitted herewith to reflect the same change. Applicant wishes to clarify that priority to these applications is *not* being claimed in this application. Priority is claimed *only* to U.S. Provisional Patent Application 60/453,846, filed March 10, 2003.

Claims 1, 5, 11, 19 and 20 have been amended; claims 18 and 22-25 have been cancelled; and claims 26-28 have been added. Claims 1, 5 and 11 have been amended to more clearly describe the claimed medical tubular structures and provide consistent claim terminology. Claim 5 has additionally been amended to delete reference to certain subject matter. Claims 19 and 20 have been amended to correct the claim dependency in light of the cancellation of claim 18 and to clarify the claimed subject matter. Claim 26 has been added to recite an intracorporeal medical device comprising an operating head and a catheter, wherein the catheter comprises a medical tubular structure of claim 1. Claim 27 further specifies that the operating head comprises a cutter and claim 28 further specifies that the catheter comprises multiple sections having different flexibility properties and the distal section comprises a medical tubular structure of claim 1. It is urged that support for all the above amendments is found throughout the specification as originally filed and that none of the amendments constitutes new matter or raises new issues for consideration. Entry of these amendments is respectfully requested.

Applicant's medical tubular structures comprise an overlying layer and a support layer defining an internal lumen, wherein the support layer, provided as a coil or braid or weave element, is attached to the overlying layer at a bonding point, but is not attached to the overlying

layer along a free portion, providing relative movement, or slipping, of the support layer and overlying layer when the tubular structure is bent. This relative movement, or slipping of the layers relative to one another when the tubular structure is bent, surprisingly provides a highly flexible structure with sufficient mechanical integrity and pushability to function as an interventional catheter. Tubular structures having this configuration also reduce the incidence of kinking, simply by virtue of the relative movement of the layers with respect to one another. This was a surprising discovery and, to the best of Applicant's knowledge, ran counter to the conventional wisdom that a supporting layer such as a coil or braid is generally sandwiched between or bonded to adjacent polymeric layers, preventing relative movement of the adjacent layers.

Claim Rejections – §112

Claims 18-21 stand rejected under 35 U.S.C. §112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant submits that this rejection is rendered moot in view of the above amendments and must be withdrawn. Claim 18 has been cancelled and claim 20 has been amended to positively recite “a” drive system.

Claim Rejections – Samson et al.

Claims 1-3, 5-9, 11-16, 18 and 19 stand rejected under 35 USC §102(b) as being anticipated by *Samson et al.*, U.S. Patent 6,143,013. Claims 4, 10 and 17 stand rejected under 35 USC §103(a) as being obvious over *Samson et al.* These rejections are respectfully traversed in view of the above amendments and the following remarks.

Samson et al. disclose high performance braided catheters having a braided metallic reinforcing member, typically formed from a super-elastic alloy ribbon, positioned between a flexible outer tubing member and an inner tubing member to produce a catheter section that is very flexible and highly kink resistant. As noted in the specification, the use of braids in a catheter body is not new (*See, e.g.*, Col. 2, line 35). The ribbon braid disclosed by *Samson et al.* is generally located between inner and outer polymeric (tubular) members that, by some mechanism, are tacky to each other (across the braid) or are bonded to one another. (*See, e.g.*,

Col. 10, lines 47-59). The polymers forming the inner and outer layer are generally melt-compatible or melt-miscible and consequently “hold fast to” the braid located between them. (See, e.g., Col. 7, lines 62-67.) When the outer tubing member is assembled with the inter liner tube and the braid, contact regions are provided between the outer covering member and the inner liner member, and open areas between the turns of the braid desirably allow the contact. (See, e.g., Col. 11, lines 43-49.) The “inner assembly” composed of the braid and the inner member may be dipped in a molten or latex liquid, in which situation contact between the outer and inner members, across the braid, is “inevitable.” (See, e.g., Col. 11, lines 49-53.) These disclosures teach the desirability of the contacting and, indeed bonding, of an outer layer and an inner layer having an interposed super-elastic braid, to one another.

It appears to Applicant that the kink resistant properties of the catheters disclosed by *Samson et al.* is attributable to the super-elastic alloy construction of the braided member which, after being deformed, returns to its original configuration. Applicant would characterize this type of catheter as being kink-recoverable, rather than kink-resistant, because the super-elastic braid forming the catheter rapidly returns to its original configuration, but isn’t otherwise “resistant” to bending or kinking.

The Examiner points to Fig. 15 and, specifically, solder junction 406, as a “bonding point.” Applicant reads this reference to teach providing a solder joint at 406 between a metallic braid (408) and a metallic proximal section (402) to create an electrical pathway for electrolytic detachment mechanisms. This does not change the “sticky” or bonded relationship between the overlying layer and the support layer/braid; it merely provides a solder joint between the support layer/braid and another metallic section, thereby providing an electrical pathway.

Applicant’s invention, and the pending claims, are directed to medical tubular structures comprising at least two layers defining an internal lumen, wherein the support layer, having a plurality of loops (e.g., a coil) is attached to the overlying layer at a bonding point, but is not attached to the overlying layer along a free portion, whereby the support layer in the free portion is slippable relative to the overlying layer when the tubular structure is bent. Thus, preserving the ability of a support layer and an overlying layer to move relative to one another when the tubular structure is bent is a critical feature of applicant’s claimed tubular structures.

Applicant perceives not only that *Samson et al.* don't disclose this feature, but they teach against both the claimed structure and the desirability of the claimed structure by teaching, for example, that polymeric layers between which a braid is positioned are tacky or bonded to one another, or are dipped in a material that holds fast to the braid located between them. Applicant does not perceive that *Samson et al.* disclose, or suggest, the medical tubular structures identified in applicant's pending claims. Applicant also does not perceive that *Samson et al.* provide any teaching that would render applicant's claimed structures obvious to one of ordinary skill in the art.

Claim Rejections – §102 (b) – Ressemann et al.

Claims 18, 20 and 21 stand rejected under 35 USC §102(b) as being anticipated by *Ressemann et al.*, U.S. Patent 5,501,694. This rejection is respectfully traversed in view of the above amendments and the following remarks.

Claim 18 has been cancelled and new claim 26 recites an intracorporeal medical device comprising an operating head and a catheter comprising a medical tubular structure of claim 1. In response to this rejection, Applicant will therefore direct remarks to the tubular structure as recited in claim 1.

Ressemann et al. disclose an expandable removal element for an atherectomy device mounted on a rotatable drive shaft. A catheter surrounds a portion of the drive shaft and is shiftable with respect to the drive shaft to adjust the removal element between an expanded and contracted condition. The drive shaft may have a heat-shrinkable sheath provided as a coating to reduce friction between the drive shaft and the catheter sheath, or the aspirated material in the lumen of the catheter sheath, to provide increased torsional rigidity to the drive shaft, to limit radial expansion of the drive shaft, and to provide a fluid-tight drive shaft lumen.

Applicant's invention, and the pending claims, are directed to medical tubular structures comprising at least two layers defining an internal lumen, wherein the support layer, having a plurality of loops (e.g., a coil) is attached to the overlying layer at a bonding point, but is *not* attached to the overlying layer along a free portion, whereby the support layer, at the free portion, is slippable relative to the overlying layer when the tubular structure is bent. Thus, preserving the ability of a support layer and an overlying layer to move relative to one another

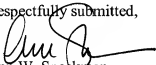
when the tubular structure is bent is a critical feature of applicant's claimed tubular structures. Applicant does not perceive any teachings in Ressemann et al. that disclose or suggest this multi-layer tubular structure, or the desirability of this feature and submits that applicant's claims are not anticipated by *Ressemann et al.*

Conclusion

In view of the above amendments and remarks, applicant believes that the pending claims are now in condition for allowance. Early reconsideration and allowance of pending claims 1-17, 19-21 and 26-28 is respectfully requested.

The Examiner is invited to telephone the undersigned at 206.382.1191 if he has questions or if a discussion of the pending claims or the prior art references relied upon for rejection would be beneficial.

Respectfully submitted,


Ann W. Speckman
Registration No. 31,881

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SPECKMAN LAW GROUP PLLC
20601